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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/590,435 | 08/23/2006 | Paul Fraser | 090931-380575 | 1436 |

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| EXAMINER | |
|---|---|
| BALLARD, KIMBERLY | |
| ART UNIT | PAPER NUMBER |
| 1649 | |

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| 12/14/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/590,435 | FRASER, PAUL | |
| | Examiner | Art Unit | |
| | Kimberly Ballard | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3,9-11,13-16,32-35,40-50 and 57-61* is/are pending in the application.

4a) Of the above claim(s) *32-35,40-50 and 57-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9-11 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/04/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Application, Amendments and/or Claims*

1. Claims 1-3, 9-11 and 13-16 have been amended and claims 4 and 12 were canceled in the amendment filed July 31, 2009. Following the amendment, claims 1-3,9-11, 13-16, 32-35, 40-50 and 57-61 are pending in the present application.

### *Election/Restrictions*

2. Applicant's election with traverse of Group I, claims 1-3, 9-11 and 13-16, in the reply filed on July 31, 2009 is acknowledged. The traversal is on the ground(s) that the methods of Groups II-IV are directed to use of the agent of Group I, and would therefore not require additional searching nor would it be an undue burden on the examiner. This is not found persuasive because this application is a 371 national stage application, and therefore is subject to Unity of Invention consideration under PCT Rule 13.1 and 13.2 (see MPEP § 1800) and not U.S. restriction practice such as for applications filed under 35 U.S.C. 111. Therefore, whether or not an undue burden for examination exists is not considered relevant to the instant situation because search burden is not a factor used to determine unity of invention or lack thereof. The basis for the lack of unity in the instant application was set forth in the restriction requirement mailed April 1, 2009. Specifically, because the technical feature linking Groups I-IV was disclosed in the prior art, it does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Therefore, the different groups are said to lack unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 32-35, 40-50, and 57-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 31, 2009.

4. Claims **1-3, 9-11** and **13-16** are under examination in the current office action.

### *Information Disclosure Statement*

5. The information disclosure statement (IDS) submitted September 4, 2009 has been considered and is of record.

### *Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 9-11 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2002/0119926 A1 to Fraser (published August 29, 2002).

Claim 1 recites an antifibrillogenic agent for inhibiting amyloidosis and/or for cytoprotection comprising a peptide consisting essentially of ANX (SEQ ID NO: 28),

wherein X is any amino acid except cysteine, or an isomer thereof, a retro or a retro-inverso isomer thereof, or a salt thereof. Dependent claims recite that X is isoleucine (I) or phenylalanine (F) (claims 2-3), that the peptide is ANX (SEQ ID NO: 28) with X being any amino acid expect cysteine (claim 9), the peptide is ANX with X being I or F (claim 10), or the peptide is ANF (SEQ ID NO: 24) (claim 11), the amyloidosis is IAPP-related (claim 13), or the amyloidosis is type I or type 2 diabetes (claim 14). Claims 15 and 16 recite a composition for inhibiting amyloidosis and/or for cytoprotection, comprising a therapeutically effect amount of the antifibrillogenic agent of claim 1 or claim 9, respectively, in association with a pharmaceutically-acceptable carrier.

Fraser teaches antifibrillogenic agents, and compositions thereof, for inhibiting amyloidosis and/or for cytoprotection (see abstract and paragraph [0075]). The agents are taught to include peptides or isomers, retro or retro-inverso isomers, peptidomimetics, or salts thereof (see [0068]). For example, Fraser discloses the peptides LANFLV (SEQ ID NO: 6) and ANFLVH (SEQ ID NO: 7), both of which comprise the peptide ANF, which is the instantly recited SEQ ID NO: 24, or the instant SEQ ID NO: 28 (ANX) wherein X is F. These peptides are evidenced to have inhibitory activity

With respect to claims 1-3, 13 and 14, which recite a peptide "consisting essentially of ANX (or ANF)", the transitional phrase limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). MPEP 2105 § states:

> If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

See also MPEP § 2111.03, which states that:

> For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355.

In the instant case, the only clear indication in the specification of the basic and novel characteristic of the invention is "antifibrillogenic agents and peptides that which are cpapable of controlling IAPP aggregation and amyloid formation" (see p. 5, lines 4-6). Because the prior art reference by Fraser is using the peptides for the same purpose and recognizes the same therapeutic effect to be had by the administration of such peptides (i.e., treatment of type I or type II diabetes, for example, see [0030]), there is nothing in the Fraser reference that would affect the basic and novel characteristic of the claimed invention. Accordingly, the claims can be construed as reciting "comprising" language.

Regarding claims 9-11, which recite that the peptide is ANX or ANF, Fraser teaches that antifibrillogenic agents of the invention may be derived from the peptides by substituting, removing or inserting one or more amino acid residues (see [0097). Accordingly, removal of three amino acid residues each from Fraser's disclosed LANFLV or ANFLVH would result in the instantly recited ANF peptide. Thus the teachings of Fraser encompass the claimed peptides.

As mentioned above, with respect to claims 13 and 14, Fraser teaches that the antifibrillogenic agents of the invention may be used for the treatment of type I or type II diabetes (see [0030]) and other amyloidoses (see [0066]), such as to control IAPP aggregation in IAPP-related amyloidosis (see [0074] and claim 13 on p. 16).

And finally, regarding claims 15 and 16, Fraser teaches compositions comprising a therapeutically effective amount of the antifibrillogenic agents in association with a pharmaceutically acceptable carrier (see [0078]).

As such, the teachings of Fraser anticipate the present invention of claims 1-3, 9-11 and 13-16.

## ***Conclusion***

8. No claims are allowed.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Ballard whose telephone number is 571-272-2150. The examiner can normally be reached on Monday-Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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